

## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:  Davies Collison Cave Level 15 1 Nicholson Street MELBOURNE VIC 3000  <i>24 Feb 24-4-04</i>	PCT NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION  (PCT Rule 44.1) Date of mailing (day/month/year) 24 FEB 2004
Applicant's or agent's file reference 12384740	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/AU2003/001665	International filing date 12 December 2003
Applicant Monash University (et al.)	

☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

## Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland  
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

## Reminders

Shortly after 18 months from the priority date, the international application will be published by the International Bureau.

If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized officer  JULIE GALE Telephone No. (02) 6283 2272
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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 12384740	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/AU2003/001665	International filing date (day/month/year) 12 December 2003	(Earliest) Priority Date (day/month/year) 12 December 2002
Applicant Monash University (et al.)		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title, ☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows: Method

Method of diagnosis, treatment and useful agents for conditions characterised by modulation in the level of activin  $\beta$ c.

5. With regard to the abstract, ☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure

☐ because this figure better characterizes the invention

☒ None of the figures

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2003/001665

**Box I** Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos : 59-64  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
Claims 59-64 relate to a pharmaceutical agent comprising an agent and to the use of an agent which is capable of modulating the functionally effective level of activin  $\beta$ c subunit. The agent is not defined other than by its mode of action. The scope of the term "agent" is so broad and indeterminate that a meaningful search could not be carried out. The scope may encompass already known compounds.
3. ☐ Claims Nos :  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box II** Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2003/001665

**A. CLASSIFICATION OF SUBJECT MATTER**Int. Cl. <sup>7</sup>: G01N 33/53; 33/574; A61K 39/395; A61P 35/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

G01N 33/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPIDS; Medline; CA (activin beta/bc/C; inhibin; modulat\*; screen, assay, diagnos\*, immunoassay, quantif\*)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1998/22492 A1 (THE REGENTS OF THE UNIVERSITY OF MICHIGAN) 28 May 1998. Whole document.	1-58
X,Y	Mellor, S.L. et al. (2000), Journal of Clinical Endocrinology & Metabolism, vol. 85(12), pp 4851-4858. "Localization of activin $\beta_A$ -, $\beta_B$ -, and $\beta_C$ -subunits in human prostate and evidence for formation of new activin heterodimers of $\beta_C$ -subunit". Whole document.	1-58

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

- \* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search  
17 February 2004Date of mailing of the international search report  
24 FEB 2004Name and mailing address of the ISA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@ipaustalia.gov.au  
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Authorized officer

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2003/001665

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 174 149 A1(KYOWA HAKKO KOGYO CO., LTD.) 23 January 2002 Whole document.	1-58
P,X	Gold, E. J. et al., (2003 Mar 28), Molecular and Cellular Endocrinology, vol. 201, pp. 143-153. "Changes in activin and activin receptor subunit expression in rat liver during the development of CCl <sub>4</sub> -induced cirrhosis". Whole document.	1-58
P,X	Mellor, S.L. et al. (2003 Oct), Endocrinology, vol. 144(10), pp. 4410-4419. "Activin $\beta$ c-subunit heterodimers provide a new mechanism of regulating activin levels in the prostate". Whole document.	1-58
X	Vejda, S. et al. (2002, Apr), Journal of Molecular Endocrinology, vol. 28, pp. 137-148. Expression and dimerization of the rat activin subunits $\beta$ c and $\beta$ e: evidence for the formation of novel activin dimers". Whole document.	33, 34
X	Thomas, T. Z. et al., (1998), The Prostate, vol. 34, pp. 34-43. "Inhibins, activins and follistatins: expression of mRNAs and cellular localization in tissues from men with benign prostatic hyperplasia". See Table I.	33
A	Whole document.	1-32, 34-58
X, Y	Risbridger, G.P. et al., (2001), Molecular and Cellular Endocrinology, vol. 180, pp. 149-153. "The contribution of inhibins and activins to malignant prostate disease". Whole document.	1-58
X	Dowling C.R. and Risbridger, G.P. (2000), Endocrine-Related Cancer, vol. 7, pp. 243-256. "The role of inhibins and activins in prostate cancer pathogenesis". Whole document.	1-58
X	Wakui, M. et al., (2001), Biochemical and Biophysical Research Communications, vol. 282, pp. 200-206. "Genes highly expressed in the early phase murine graft-versus-host reaction". Whole document.	1-3, 6, 11-13, 30, 33, 37, 42, 44, 46-48, 53, 55
X	GenexBioscience, Sept 2002: 'Anti-activin beta-C: polyclonal antibody produced in rabbits immunized with a synthetic KLH-conjugated peptide'. Retrieved 5 February 2004 URL: <a href="http://www.genexbioscience.com/products.cfm?productID=146">http://www.genexbioscience.com/products.cfm?productID=146</a> . Also, waybackmachine: <a href="http://web.archive.org/web/*/www.genexbioscience.com">http://web.archive.org/web/*/www.genexbioscience.com</a> , retrieved on 5 February 2002.	33-35

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/AU2003/001665**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	9822492	AU	53567/98	CA	2272545	EP	0960118
EP	1174149	AU	38394/00	CA	2365449	WO	0062809
END OF ANNEX							

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